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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/907,001	07/16/2001	Thomas D. Yager	VGEN.P-015-DV-2	8061

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HOLLAND & HART, LLP
555 17TH STREET, SUITE 3200
DENVER, CO 80201

EXAMINER	
BARTON, JEFFREY THOMAS	

ART UNIT	PAPER NUMBER
1753	

DATE MAILED: 10/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

S.C.

Office Action Summary	Application No.	Applicant(s)	
	09/907,001	YAGER ET AL.	
	Examiner	Art Unit	
	Jeffrey T. Barton	1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *20011106*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The disclosure is objected to because of the citation of an erroneous date. In the preliminary amendment received on 16 July 2001, the filing date of Application No. 08/973,933 is given as February 16, 1997, although the filing date (i.e. 371 date) of the application is December 16, 1997.

Appropriate correction is required.

Claim Objections

2. Claim 24 is objected to because the word "fullerenes" is misspelled as "fullerences" in line 5 of the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 24, 25, 27, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soane et al in view of Jinno et al, Ross et al, and either Ekström et al or Kaltenbach et al.

Addressing claim 24:

Soane et al discloses a method of manufacturing a microelectrophoresis chip (Figure 1), the chip comprising a substrate (1) having a channel (2) for performing a separation, at least two electrodes (4-9, 4' - 9') disposed within the channel, a homogeneous separation medium (3) in the channel, a detector element for observation of migrating biopolymers (Column 7, line 66 - Column 8, line 10), wherein the method

comprises the steps of: lithographically forming the channel of the device (Column 5, lines 36-39), forming at least two electrodes within the channel (Column 4, line 63 - Column 5, line 11), and filling the channel with a homogeneous separation medium. (Column 4, lines 52-55)

Soane et al do not explicitly disclose using a separation medium comprising water-soluble fullerenes or lithographically forming the channel according to claimed steps a-c.

Jinno et al disclose the use of buckminsterfullerene as a chromatographic stationary phase having unique selectivity for the analyzed compounds. (Abstract, Introduction section)

Ross et al disclose the preparation of water-soluble fullerenes (Abstract)

Ekström et al disclose a method of preparing a microfluidic chip comprising the steps of: lithographically forming a mold that is a reverse of the desired channel structures (Column 4, line 61 - Column 5, line 30); casting or imprinting the channels in a polymeric substrate as a negative impression of the mold (Column 5, lines 31-57); and fusing the polymeric substrate to a solid support (Column 6, lines 38-55)

Kaltenbach et al disclose a method of preparing a microfluidic chip comprising the steps of: lithographically forming a mold that is a reverse of the desired channel structures (Column 7, line 55 - Column 8, line 30); casting the channels in a polymeric substrate as a negative impression of the mold (Column 8, lines 16-30); and fusing the polymeric substrate to a solid support (Column 10, lines 49-55)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Soane by replacing the separation medium with a medium comprising fullerenes, as taught by Jinno et al, because Jinno et al teach that they have unique selectivity that would be useful in certain separations, and Soane et al suggest a wide range of media suitable for use in their device (Column 4, lines 52-55). The fullerenes act as obstacles to the migration of analytes, resulting in the differences in elution time. Additionally, it would have been obvious to use water-soluble fullerenes, the preparation of which was taught by Ross et al, because it would allow the use of a homogeneous aqueous phase, and would be reasonably expected to provide selectivity distinct from other aqueous separation phases, given the disclosure of Jinno et al.

It would also have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Soane by preparing the mold and forming the substrate according to steps a-c, as taught by either Ekström et al or Kaltenbach et al, because Soane et al state that conventional lithographic techniques can be used to produce their device (Column 5, lines 36-39), and the devices produced by Ekström et al and Kaltenbach et al are similar in structure and function to those of Soane et al.

Addressing claims 25, 27, and 28:

Regarding claim 25, Soane et al disclose the channel being 5-25 microns in depth. (Column 4, lines 43-47)

Regarding claim 27, Soane et al disclose a plurality of anodes and cathodes being disposed in the channel. (Figure 1; Column 7, lines 18-24, 48-56)

Regarding claim 28, Soane et al disclose the disposition of electrodes to generate fields in at least two non-parallel directions. (Column 7, lines 18-24; Column 8, lines 11-20)

7. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Soane et al, Jinno et al, Ross et al, and either Ekström et al or Kaltenbach et al as applied to claim 24 above, and further in view of Sethi et al.

Soane et al, Jinno et al, Ross et al, and either Ekström et al or Kaltenbach et al disclose methods as described above in paragraph 6. In addition, Soane et al suggest plural elements being encompassed by their disclosure. (Column 4, lines 20-23)

None among Soane et al, Jinno et al, Ross et al, Ekström et al, and Kaltenbach et al explicitly disclose the preparation of plural separation channels in a substrate.

Sethi et al disclose lithographic preparation of several separation channels in a single substrate. (Figure 11)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combined methods of Soane et al, Jinno et al, Ross et al, and either Ekström et al or Kaltenbach et al by fabricating plural separation channels on the substrate, as taught by Sethi et al, because Soane et al suggest such multiple features and it would allow parallel separations in a single device.

8. Claims 29, 30, 32, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soane et al in view of Tanaka et al, Newkome et al, and either Ekström et al or Kaltenbach et al.

Addressing claim 29:

Soane et al discloses a method of manufacturing a microelectrophoresis chip (Figure 1), the chip comprising a substrate (1) having a channel (2) for performing a separation, at least two electrodes (4-9, 4' - 9') disposed within the channel, a homogeneous separation medium (3) in the channel, a detector element for observation of migrating biopolymers (Column 7, line 66 - Column 8, line 10), wherein the method comprises the steps of: lithographically forming the channel of the device (Column 5, lines 36-39), forming at least two electrodes within the channel (Column 4, line 63 - Column 5, line 11), and filling the channel with a homogeneous separation medium. (Column 4, lines 52-55)

Soane et al do not explicitly disclose using a separation medium comprising self-assembling dendrimers or lithographically forming the channel according to claimed steps a-c.

Tanaka et al disclose using dendrimers as carriers in an electrophoretic separation, in which the separation was influenced by differential binding of the analytes to the dendrimers and dendrimer size. (Abstract, Figures 1 and 2) The size and binding effects show the dendrimers acting as obstacles to analyte migration.

Newkome et al disclose the preparation of self-assembling dendrimers. (Abstract, Experimental section)

Ekström et al disclose a method of preparing a microfluidic chip comprising the steps of: lithographically forming a mold that is a reverse of the desired channel structures (Column 4, line 61 - Column 5, line 30); casting or imprinting the channels in a polymeric substrate as a negative impression of the mold (Column 5, lines 31-57); and fusing the polymeric substrate to a solid support (Column 6, lines 38-55)

Kaltenbach et al disclose a method of preparing a microfluidic chip comprising the steps of: lithographically forming a mold that is a reverse of the desired channel structures (Column 7, line 55 - Column 8, line 30); casting the channels in a polymeric substrate as a negative impression of the mold (Column 8, lines 16-30); and fusing the polymeric substrate to a solid support (Column 10, lines 49-55)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Soane by replacing the separation medium with a medium comprising dendrimers, as taught by Tanaka et al, because Tanaka et al teach that dendrimers work well as an alternative to surfactants and their use results in different selectivity that would be useful in certain separations (Page 959-960), and Soane et al suggest a wide range of media suitable for use in their device (Column 4, lines 52-55). Additionally, it would have been obvious to use self-assembling dendrimers, the preparation of which was taught by Newkome et al, because it would simplify dendrimer synthesis, and they would be reasonably expected to provide similar benefits to those disclosed by Tanaka et al.

It would also have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Soane by preparing the mold and

forming the substrate according to steps a-c, as taught by either Ekström et al or Kaltenbach et al, because Soane et al state that conventional lithographic techniques can be used to produce their device (Column 5, lines 36-39), and the devices produced by Ekström et al and Kaltenbach et al are similar in structure and function to those of Soane et al.

Addressing claims 30, 32, and 33:

Regarding claim 30, Soane et al disclose the channel being 5-25 microns in depth. (Column 4, lines 43-47)

Regarding claim 32, Soane et al disclose a plurality of anodes and cathodes being disposed in the channel. (Figure 1; Column 7, lines 18-24, 48-56)

Regarding claim 33, Soane et al disclose the disposition of electrodes to generate fields in at least two non-parallel directions. (Column 7, lines 18-24; Column 8, lines 11-20)

9. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Soane et al, Tanaka et al, Newkome et al, and either Ekström et al or Kaltenbach et al as applied to claim 29 above, and further in view of Sethi et al.

Soane et al, Tanaka et al, Newkome et al, and either Ekström et al or Kaltenbach et al disclose methods as described above in paragraph 8. In addition, Soane et al suggest plural elements being encompassed by their disclosure. (Column 4, lines 20-23)

None among Soane et al, Tanaka et al, Newkome et al, Ekström et al, and Kaltenbach et al explicitly disclose the preparation of plural separation channels in a substrate.

Sethi et al disclose lithographic preparation of several separation channels in a single substrate. (Figure 11)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combined methods of Soane et al, Tanaka et al, Newkome et al, and either Ekström et al or Kaltenbach et al by fabricating plural separation channels on the substrate, as taught by Sethi et al, because Soane et al suggest such multiple features and it would allow parallel separations in a single device.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Jeffrey Barton, whose telephone number is (571) 272-1307. The examiner can normally be reached Monday-Friday from 8:30 am – 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached at (571) 272-1342. The fax number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

JTB
October 15, 2004

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